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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,636	06/02/2008	Didier Serteyn	9248-88834-US	4258

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
08/25/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/597,636	SERTEYN ET AL.
	Examiner	Art Unit
	GAILENE R. GABEL	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,17-24,26-32,34-37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) *24 and 27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,17-23,26,32,34-37,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2011 has been entered.

Amendment Entry

2. Applicant's amendment and response, filed July 6, 2011, is acknowledged and has been entered. Claims 15, 19, 21, 26, 37, and 39 have been amended. Claims 33 and 38 have been cancelled. Claims 24 and 27-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 15, 17-24, 26-32, 34-37, 39, and 40 are pending. Claims 15, 17-23, 26, 32, 34-37, 39, and 40 are under examination.

Amendment Entry

3. Any rejections or objections not reiterated herein, have been withdrawn.

4. The rejections of claims 33 and 38 are now moot in light of Applicant's cancellation of the claim.

5. In light of Applicant's amendment and arguments, the rejection of claims 26, 37, and 39 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

6. In light of Applicant's amendment and arguments, the rejection of claims 15, 17-19, 23, 26, 32, 37, and 40 under 35 U.S.C. 102 (b) as being anticipated by Deby et al. (US Patent 5,460,961), is hereby, withdrawn.

7. In light of Applicant's amendment and arguments, the rejections of claims 20-22, 34-36, and 39 under 35 U.S.C. 103(a) as being unpatentable over Deby et al. (US Patent 5,460,961) in view of each one of Hansel et al. (WO 99/61907), Deby-Dupont et al. (Equine Neutrophil Myeloperoxidase in Plasma: design of a radio-immunoassay and first results in septic pathologies, Veterinary Immunology and Immunopathology 66:257-271 (1998)), Terao et al. (US Patent 5,290,679), and Wilson et al. (US 2006/0257879), are hereby, withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 15, 17-21, 26, 32, 34, 36, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchida et al. (US Patent 5,552,292).

Uchida et al. disclose a kit and method of measuring activation status of neutrophil cells in a biological sample containing neutrophils and/or enzyme released by the neutrophils to provide indication of disease or pathology (inflammatory gastrointestinal disorder, colon cancer). The enzymes released by the neutrophils include active oxygen species produced and released by activated neutrophils including myeloperoxidase (MPO) and elastase (Abstract; col. 2, lines 10-41). According to Uchida et al., the enzyme granules released are found in serum, saliva, breast milk, and faecal derived samples (col. 2, lines 61-64). In practice, Uchida et al. teach immunocapturing enzyme, i.e. MPO or elastase, released by neutrophil cells present in the sample by contacting the sample with solid phase immobilized "immunocapture" antibodies that are specific for and bind to the released neutrophil enzyme. Uchida et al. further teach detecting and/or measuring the amount of the immunocaptured enzyme released by the neutrophil cells using methods such as enzyme-linked immunosorbent assay (ELISA) or latex agglutination. The amount of released enzyme content provides indication of the activation status of the activated neutrophil cells (col. 3, line 61 to col. 4, line 25; col. 7, lines 15-18; Example 3). The amount of released active enzyme is compared to a reference value from subjects without disease (col. 4, lines 26-62; Table 2). Uchida et al. teach washing steps and using peroxidase as enzyme label in ELISA (col. 5, lines 5-7; Example 2)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 23 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) in view of Deby et al. (US Patent 5,460,961).

Uchida et al. is discussed supra. Uchida et al. differs from the instant invention in failing to teach adding nitrite to the reaction medium.

Deby et al. disclose a kit and ELISA method for immunological detection of recombinant myeloperoxidase (MPO) and its activity in a biological sample containing neutrophils. Deby et al. teach using antibodies effective for capturing the enzyme and chromogenic substrate effective for detecting and measuring the enzyme. Deby et al. teach that an effective amount of nitrite in the form of sodium salt or any other form of

earth alkali salt can be added into the reaction medium so as to enable generation of enhanced signal during measurement (col. 21, line 36 to col. 22, line 6).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate nitrite as taught by Deby into the method of Uchida to immunologically capture and detect active enzyme released by neutrophils because Deby taught that an effective amount of nitrite can be added to the reaction medium in enzyme assays to generate enhanced enzymatic signal in enzyme measurement procedures.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) view of Deby-Dupont et al. (Equine Neutrophil Myeloperoxidase in Plasma: design of a radio-immunoassay and first results in septic pathologies, Veterinary Immunology and Immunopathology 66: 257-271 (1998)).

Uchida et al. is discussed supra. Uchida et al. differ from the instant invention in failing to teach that the mammal is a horse.

Deby-Dupont et al. teach obtaining specific antiserum against MPO and immunologically assaying for the presence and amount of MPO in horses and determining pathological conditions such as strangulation intestinal pathologies which are accompanied by local activation of neutrophils. Such conditions can be revealed by measuring tissular enzymatic activity of the granulocytic enzyme: MPO using the specific antibody (antiserum) to MPO (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to immunologically assay for the amount and activity of enzyme MPO

as taught by Uchida, in a blood sample obtained from a horse as taught by Deby-Dupont because Uchida specifically taught that polyclonal and monoclonal antibodies can be used in immunological enzyme assay methods to specifically capture and detect and measure content and activity of MPO from neutrophils and Deby-Dupont expressly showed the significance of specifically measuring accurate level and activity of MPO in determining conditions such as strangulation intestinal pathologies in horses which occurs by local activation of granulocytes, i.e. neutrophils.

11. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent 5,552,292) in view of Wilson et al. (US 2006/0257879).

Uchida et al. is discussed supra. Uchida et al. differ from the instant invention in failing to teach a substrate which is 10-acetyl-3,7-dihydroxyphenoxazine.

Wilson et al. teach that peroxidase activity is present in many cells and that many fluorogenic substrates for horseradish peroxidase are well known in the art and are commercially available in ELISA kits. Wilson et al. specifically teach that 10-acetyl-3,7-dihydroxyphenoxazine is a well-known fluorogenic substrate which is advantageous for its ability to react with hydrogen peroxide in the presence of horseradish peroxidase and produce highly fluorescent resolution signal.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate 10-acetyl-3,7-dihydroxyphenoxazine as a fluorogenic substrate into the method of Uchida in immunologically detecting and measuring level and activity of MPO because 10-acetyl-3,7-dihydroxyphenoxazine appears to be an

obvious variation of fluorogenic substrate known and used in immunological enzyme assay methods such as taught Uchida, which is advantageous for its ability to produce highly fluorescent resolution signal.

Remarks

12. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Carson et al. (US Patent 5,698,518) disclose monoclonal antibodies HEL 1076 and HAT 1099 as capture and detection antibodies for neutrophil elastase to measure neutrophil elastase activity (Example 3).

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

August 24, 2011